Notice of Allowability	Application No.	Applicant(s)	
	10/602,394	HASKELL-LUEVANO, CARRIE	
	Examiner	Art Unit	
	Satyanarayana R. Gudibande	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *12/20/2005*.

2. ☒ The allowed claim(s) is/are *29-43*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 4/6/05, 9/2/03
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of group I invention (claims 1-8 and 13-20) in the reply filed on January 25, 2006 is acknowledged. Canceling of claims 4, 9-12, 16 and 21-27 and addition of claim 28 via a preliminary amendment filed on December 20, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Examiner searched Seq ID No. 3 and found to be free of art. Examiner continued the search to other species and found them to be free of art.

Claim 28 was included in the examination of the instant application.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Margaret Efron on March 02, 2006.

The application has been amended as follows:

IN THE CLAIMS:

Cancel claims 1-3, 5-8, 13-15, 17-20 and 28.

Enter new claims 29-43 as follows:

29. A peptide that is biologically active at melanocortin receptors comprising an AGRP (109-118) analogue template of SEQ ID No: 3 wherein AGRP (111-113) residues of the AGRP (109-118) template are substituted with a melanocortin agonist-based bioactive determinant sequence wherein
a) the melanocortin agonist-based bioactive determinant sequence is selected from the group consisting of:
i) Trp-Arg-Phe
ii) Trp-Arg-Phe
iii) Phe-Arg-Trp
iv) DPhe-Arg-Trp
v) His-Phe-Arg-Trp; and
vi) His-DPhe-Arg-Trp.

30. The peptide according to claim 29, wherein the peptide is of any SEQ ID Nos. 4-7, 9 and 10.

31. A peptide that is biologically active at melanocortin receptors comprising an AGRP (109-118) analogue template of SEQ ID No: 3, wherein AGRP (111-113) residues of the AGRP(109-118) template are substituted with the sequence

Xaa1-Xaa2-Xaa3-Xaa4

wherein Xaa1 is selected from His, Ala, Atc, Bip, Lys, Nal(1'), Nal(2'), (pI)Phe and Tic, or is absent;
Xaa2 is selected from Trp, Phe, DPhe, , Ala, Atc, Bip, Lys, Nal(1'), Nal(2'), (pI)Phe and Tic,
Xaa3 is selected from Arg, Ala, Atc, Bip, Lys, Nal(1'), Nal(2'), (pI)Phe and Tic;
Xaa4 is selected from Phe, DPhe, Trp, Ala, Atc, Bip, Lys, Nal(1'), Nal(2'), (pI)Phe and Tic; and
wherein, at least one of Xaa1, Xaa2, Xaa3 or Xaa4 is selected from Ala, Atc, Bip, Lys, Nal(1'), Nal(2'), (pI)Phe and Tic.

32. A peptide that is biologically active at melanocortin receptors comprising a sequence selected from the group consisting of SEQ ID Nos: 2 and 24-43.

33. The peptide according to claim 29, wherein the peptide further comprises a lactam bridge that is substituted for the disulfide bridge of the AGRP (109-118) analogue template.

34. The peptide according to claim 33, wherein the peptide is SEQ ID No: 11.

35. The peptide according to claim 33, wherein the peptide further comprises a second and a third bioactive determinant sequences at the N-terminal and C-terminal, respectively, wherein the second bioactive determinant sequence at the N-terminal is Ser-Tyr-Ser-Nle (amino acid residues 2-5 of SEQ ID No: 11) and the third bioactive determinant sequence at the C-terminal is Lys-Pro-Val amino acid residues.

36. A pharmaceutical composition comprising a peptide that is biologically active at melanocortin receptors comprising an AGRP (109-118) analogue template of SEQ ID No: 3 wherein AGRP (111-113) residues of the AGRP (109-118) template are substituted with a melanocortin agonist-based bioactive determinant sequence wherein
a) the melanocortin agonist-based bioactive determinant sequence is selected from the group consisting of:
i) Trp-Arg-Phe
ii) Trp-Arg-Phe
iii) Phe-Arg-Trp
iv) DPhe-Arg-Trp
v) His-Phe-Arg-Trp; and
vi) His-DPhe-Arg-Trp.

37. The pharmaceutical composition according to claim 36, wherein the peptide is of any SEQ ID Nos. 4-7, 9 and 10.

38. A pharmaceutical composition comprising a peptide that is biologically active at melanocortin receptors comprising an AGRP (109-118) analogue template of SEQ ID NO: 3, wherein AGRP (111-113) residues of the AGRP (109-118) template are substituted with the sequence

Xaa1-Xaa2-Xaa3-Xaa4

wherein,
Xaa1 is selected from His, Ala, Atc, Bip, Lys, Nal(1'), Nal(2'), (pI)Phe and Tic, or is absent;
Xaa2 is selected from Trp, Phe, DPhe, , Ala, Atc, Bip, Lys, Nal(1'), Nal(2'), (pI)Phe and Tic,
Xaa3 is selected from Arg, Ala, Atc, Bip, Lys, Nal(1'), Nal(2'), (pI)Phe and Tic;
Xaa4 is selected from Phe, DPhe, Trp, Ala, Atc, Bip, Lys, Nal(1'), Nal(2'), (pI)Phe and Tic; and wherein, at least one of Xaa1, Xaa2, Xaa3 or Xaa4 is selected from Ala, Atc, Bip, Lys, Nal(1'), Nal(2'), (pI)Phe and Tic.

39. A pharmaceutical composition comprising a peptide of claim 32.

40. The pharmaceutical composition according to claim 36, wherein the peptide further comprises a lactam bridge that is substituted for the disulfide bridge of the AGRP (109-118) analogue template.

41. The pharmaceutical composition according to claim 40, wherein the peptide is of SEQ ID No. 11.

42. The pharmaceutical composition according to claim 40, wherein the peptide further comprises a second and a third bioactive determinant sequences at the N-terminal and C-terminal, respectively, wherein the second bioactive determinant sequence at the N-terminal is Ser-Tyr-Ser-Nle (amino acid residues 2-5 of SEQ ID No: 11) and the third bioactive determinant sequence at the C-terminal is Lys-Pro-Val amino acid residues.

43. The composition of claim 36, wherein the composition is an oral composition.

Reasons for Allowance

In the instant application, applicants claim a peptide that is biologically active at melanocortin receptors comprising an AGRP(109-118) analog template of Seq ID No: 3, wherein AGRP(111-113) residues of the AGRP(109-118) template are substituted with a melanocortin agonist based bioactive determinant sequence.

The following is an examiner's statement of reasons for allowance: The closest prior art, Tota, et al., Biochemistry, 1999, 38, 897-904 teaches the molecular interaction of AGRP and AGRP related proteins with human melanocortin receptors. However, the prior art does not teach or suggest, alone or in combination, the instantly claimed peptide sequences that are biologically active at melanocortin receptors.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

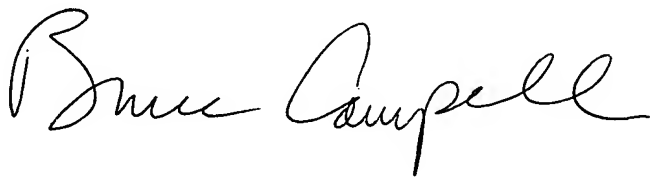
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Satyanarayana R. Gudibande, Ph.D.
Art Unit 1654



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